NEW-GENERATION PULSE OXIMETRY IN THE CARE OF CRITICALLY ILL PATIENTS

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OBJECTIVE To review the published, peer-reviewed studies to date on use of the new-generation pulse oximeters, which are manufactured with algorithms to filter out patients' body motions, and describe the application of new-generation pulse oximetry in clinical practice in critical care.

METHODS MEDLINE was used to locate appropriate articles on pulse oximetry for the years 1995 to 2003. Each article was examined for scientific merit, content, and applicability to clinical practice.

RESULTS A total of 17 relevant articles on the clinical performance of the new-generation pulse oximeters were reviewed, and the data were organized into a table.

CONCLUSIONS The combination of studies done in both clinical and laboratory settings did not provide any strong and convincing evidence that the performance of any single new-generation device was superior to that of any other new-generation device. However, the clinical performance of all the new-generation pulse oximetry devices was better than that of earlier devices. (American Journal of Critical Care. 2005;14:26-39)

Monitoring of oxygen saturation is important in the contemporary healthcare environment and is widely regarded as one of the most important advances in clinical monitoring. In fact, Hanning and Alexander-Williams1 described it as “the greatest advance in patient monitoring since electrocardiography.” Before 1980, the most common way to monitor patients continuously for hypoxemia was through physical assessment of the skin for cyanosis. However, the clinical detection of cyanosis is subjective and unreliable, and cyanosis is a late sign of hypoxemia. Oxygen saturation generally must decrease to 80% to 85% before any changes in skin color can be detected.2

Continuous monitoring of oxygen saturation via pulse oximetry is a standard of care for use in the operating room, postanesthesia care unit (PACU), critical care unit, emergency department, and environments in which conscious sedation is used.3,4 As the acuity level of hospitalized patients increased during the
past 10 years, so too did the need for oxygen saturation monitoring outside critical care areas.

The first commercially available pulse oximeter was developed by Takuo Aoyagi and was marketed by Nihon Koden in 1974. However, both this first pulse oximetry device and the Oximet marketed by Minolta in 1977 were considered primarily research devices. The first pulse oximetry device manufactured for routine clinical use was the Nellcor N-100. It was initially marketed in 1982 and became the standard conventional pulse oximeter. Those first conventional oximeters made it possible to measure oxygen saturation as a continuous parameter and, as a result, were rapidly adopted for use in surgery to prevent the estimated 40% of accidental deaths that were due to decreases in oxygen saturation. However, outside the operating room, patients’ body motions became a major technical challenge, because the motions interfere with the ability of conventional pulse oximeters to obtain an accurate measurement.

Motion artifact occurs either when a patient’s movements cause the pulse oximeter to incorrectly interpret the movements as a pulse signal or when the motion artifact prevents accurate detection of the patient’s true pulse signal. The resultant increase in false alarms and erroneous measurements can desensitize clinicians to the alarms and increase the chance of missing a clinically important true alarm.

Manufacturers of pulse oximeters have sought to reduce motion artifact in the pulse signal through improvements in the algorithms. “Motion tolerant” pulse oximetry devices are now commercially available from several different manufacturers, and as a group are referred to as “new generation” pulse oximeters. To date, peer-reviewed scientific publications on evaluations of these new-generation, motion-tolerant devices are few and are primarily limited to 3 of the devices currently on the market: FAST SpO2 (Fourier artifact suppression technology SpO2; Philips Medical Systems, Andover, Mass; first marketed in 1999), SET (signal extraction technology; Masimo Corp, Irvine, Calif; first marketed in 1998), and Oxismart (Nellcor, Pleasanton, Calif; first marketed in 1994).

## Laboratory Studies

The performance of new-generation pulse oximetry devices was evaluated in a laboratory setting in 5 studies.

Several problems in the published studies made interpretation and/or generalization of the findings difficult. First, various software revisions of each manufacturer’s algorithms for measuring oxygen saturation were used, often making the comparisons somewhat of an apples-and-oranges approach. Second, even when pulse oximetry devices with the same brand name were used, most authors did not fully disclose the actual software revision or signal averaging times used during the testing, making meaningful comparisons between studies even more difficult. Third, studies were characterized by different evaluation criteria, limited evaluation criteria, inadequate description of how device performance was evaluated, or poor study design. Last, Dumas et al evaluated a prototype that was never released commercially; that study, therefore, was excluded from this review. Comparisons, findings, strengths, and weaknesses of the reviewed studies are outlined in the Table.

### Review of the Literature

MEDLINE was used to identify research studies on the new-generation motion-tolerant pulse oximetry products published in English during the period 1995 through 2004. The search terms “oxygen saturation,” “pulse oximetry,” “SpO2,” and “oxygen measurement” were used. Even though many articles on pulse oximetry in general have been published, the focus of most of the articles was conventional pulse oximetry. In this state-of-the-science review, we focus solely on database studies on the performance of the new-generation pulse oximetry devices during patients’ movements. Although we also reviewed some data on the performance of the devices in patients with low perfusion, that aspect was not our focus. We found 17 research studies in which investigators specifically examined the performance of new-generation devices; these studies are listed and described in the Table.

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grammed to move in various patterns. The SpO₂ readings of the moving hand are then compared with the readings of the nonmoving reference hand. The disadvantage of this approach is that passive motion is used, a kind of motion that has little relevance to clinicians because these simulated passive motions do not mimic the active motion most common in patients in actual clinical settings. Therefore, the use of this

<table>
<thead>
<tr>
<th>Study</th>
<th>Devices</th>
<th>Patients</th>
</tr>
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<tr>
<td>Barker and Shah⁹</td>
<td>Masimo SET (MT): experimental prototype Nellcor N-3000 (MT) with variable signal-averaging time Nellcor N-200 (CPO)</td>
<td>10 healthy adult volunteers in a laboratory setting</td>
</tr>
<tr>
<td>Bohnhorst et al¹⁰</td>
<td>Masimo SET (MT) in 8-second signal-averaging mode Nellcor N-3000 (MT) with variable signal-averaging time Nellcor N-200 (CPO) in 6- to 7-second signal-averaging mode</td>
<td>17 patients in a NICU</td>
</tr>
<tr>
<td>Brouillette et al¹¹</td>
<td>Part I Masimo SET (MT) in 4-second signal-averaging mode Nellcor N-200 (CPO) in 2- to 3-second signal-averaging mode Nellcor N-395 in 2- to 3-second signal-averaging mode Transcutaneous oxygen probe (no model given) Part II Masimo Radical in 2-second signal-averaging mode (MT) Nellcor N-200 (CPO)</td>
<td>Part I 24 children referred to a sleep apnea laboratory because of sleep-disordered breathing Part II 22 children referred to a sleep apnea laboratory because of sleep-disordered breathing</td>
</tr>
<tr>
<td>Durbin and Rostow¹²</td>
<td>Masimo SET (MT) Arterial blood gas sample</td>
<td>13 patients with thoracic and cardiovascular conditions in an ICU</td>
</tr>
<tr>
<td>Durbin and Rostow¹³</td>
<td>Masimo SET (MT) Ohmeda 3740 (CPO)</td>
<td>59 adult cardiac surgery patients</td>
</tr>
</tbody>
</table>
type of testing is a significant flaw when used in studies to compare the performance of pulse oximetry devices, a flaw that has been recognized by other researchers.

Approaches in which active motion is used to test pulse oximetry devices have also been described. Both Jopling et al16 and Gerhing et al14 used healthy volunteers but devised active-motion protocols of tap-

<table>
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<tr>
<th>Findings</th>
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<tr>
<td>Masimo SET had the best overall performance, with 99% accuracy and a positive predictive value of 100%</td>
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<tr>
<td>N-200 had the greatest number of errors in SpO2 values, an overall accuracy of 76%, and a positive predictive value of 73%</td>
<td>The hand with the Masimo SET device was used as the reference hand</td>
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<td>N-3000 had the greatest dropout rates, an overall accuracy of 87%, and a positive predictive value of 81%</td>
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<td>Masimo SET missed 1 hypoxemic event (0.5%)</td>
<td>Signal-averaging time for the N-200 was not specified</td>
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<tr>
<td>N-3000 missed 10 hypoxemic events (5.4%)</td>
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<td>N-200 did not miss any hypoxemic events, but had the highest rate of dropouts</td>
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</table>

**Part I**

Simultaneous readings from an MT device and a CPO were compared during 20 randomly selected desaturation events of ≥4%.

With the N-200, 88% of 220 desaturations were detected during wakefulness, and 38% of 194 desaturation events during sleep were classified as motion artifact.

With the Masimo Q 400 and the transcutaneous oxygen probe, no desaturation events were detected.

A total of 119 desaturation episodes during sleep were detected by all 3 devices.

Part II

Newer version MT was compared with CPO for detection of true desaturations.

Masimo Radical device detected significantly more nonartifactual desaturation events during sleep than the N-200 did.

**Performance of an MT device was evaluated in patients whose CPO did not acquire a reliable signal.**

Masimo SET was able to obtain a reliable signal in 12 of 13 patients; the patient in whom the signal could not be detected had hypotension, poor peripheral perfusion, and shivering and was being treated with intra-aortic balloon pumping.

The difference between direct measurement of SaO2 and the Masimo SET value was 1.1% (±1%).

Two thirds of saturation values were >94%.

Researchers measured amount of data dropout, artifact, or when SpO2 readings differed from arterial blood gas results by more than 10%.

With patients randomly assigned to groups, the Masimo SET was significantly more reliable than was the CPO.

Patients with the Masimo SET were weaned to a fraction of inspired oxygen of 0.40 more quickly and had fewer arterial blood gas analyses than did the patients with the CPO.

The 2 groups did not differ in time to extubation.

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<td>The “Methods” section lacked detail on the time from application of the MT device until a reliable signal was obtained</td>
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<td>The small sample size limits generalization of the findings</td>
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<td></td>
<td>Most of the patients had normal SaO2 during the study period</td>
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<td>The results may not be applicable to other populations of patients</td>
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<td></td>
<td>Only 99 of 86 patients had enough complete data for analysis</td>
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**Findings**

- **Masimo SET** had the best overall performance, with 99% accuracy and a positive predictive value of 100%.
- **N-200** had the greatest number of errors in SpO2 values, an overall accuracy of 76%, and a positive predictive value of 73%.
- **N-3000** had the greatest dropout rates, an overall accuracy of 87%, and a positive predictive value of 81%.
- **Masimo SET** missed 1 hypoxemic event (0.5%).
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- **N-200** did not miss any hypoxemic events, but had the highest rate of dropouts.

**Comments**

- Only passive motion was tested.
- The hand with the Masimo SET device was used as the reference hand.
- The nonmotion hand was sometimes moving.
- Signal-averaging time for the N-200 was not specified.
- No data were reported on overall frequencies of false alarms.
- No gold standard reference was used.

**Parts I and II**

- Signal-averaging settings given in the abstract do not agree with those in the text.
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- Data on the accuracy of transcutaneous oxygen monitoring in children and adults were limited but theoretically are of concern because of increased skin thickness in patients other than neonates.
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ping and scratching motions with a wide variety of amplitudes and velocities. A noteworthy weakness of these studies is that both had small sample sizes (Jopling et al, N = 8; Gehring et al, N = 10). In addition to motion, the devices in these studies were tested during conditions of hypoxemia and low perfusion. Jopling et al induced hypoxemia in the healthy subjects and thus obtained a range of oxygen saturations of 70% to 100% during the active-motion testing, which provided a much closer approximation to the range of SpO₂ values that might occur in a real clinical setting. Gehring et al simulated low perfusion by compressing the brachial artery. The overall findings for the detection of hypoxemia of both of these studies indicated that the performance of the new-generation devices was better than that of the conventional devices. When the new-generation devices were compared with one another, differences in the detection of hypoxemia were not significant.

### Table: Study Devices Patients

<table>
<thead>
<tr>
<th>Study</th>
<th>Devices</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gehring et al¹⁴</td>
<td>Philips FAST Spo₂ (revision B.0; MT)</td>
<td>10 healthy volunteers in a laboratory setting</td>
</tr>
<tr>
<td></td>
<td>Masimo SET (MT)</td>
<td></td>
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<tr>
<td></td>
<td>Nellcor N-395 (MT)</td>
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<tr>
<td></td>
<td>Datex-Ohmeda 3900P (MT)</td>
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<td></td>
<td>Nellcor N-3000 (MT, but older than N-395)</td>
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<tr>
<td>Hay et al¹⁵</td>
<td>Masimo SET (MT)</td>
<td>26 infants in an NICU</td>
</tr>
<tr>
<td></td>
<td>Nellcor N-395 (MT)</td>
<td>Part I</td>
</tr>
<tr>
<td></td>
<td>MARSpo₂ (MT)</td>
<td>Part II</td>
</tr>
<tr>
<td></td>
<td>Philips FAST Spo₂ (Virida 24C; MT)</td>
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<tr>
<td></td>
<td>Nellcor N-200 (CPO)</td>
<td></td>
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<tr>
<td>Jopling et al¹⁶</td>
<td>Nellcor N-395 (MT)</td>
<td>8 subjects (the characteristics of subjects were not described)</td>
</tr>
<tr>
<td></td>
<td>Masimo SET (MT)</td>
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</tr>
<tr>
<td></td>
<td>Nellcor N-395 (MT)</td>
<td></td>
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<tr>
<td></td>
<td>NPB-290</td>
<td></td>
</tr>
<tr>
<td>Kastle and Konecny¹⁷</td>
<td>Philips M3 (revision B) FAST Spo₂ (MT)</td>
<td>Output signals derived from patients were used in a laboratory benchmark study</td>
</tr>
<tr>
<td></td>
<td>Ivy 2000 (revision 2.2) with Masimo SET (MT)</td>
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</tr>
<tr>
<td></td>
<td>Nellcor N-3000 (revision 3.03; MT)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Philips CMS (revised A.0; CPO)</td>
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</table>

In a lab setting, all new-generation pulse oximeters outperformed conventional devices in their ability to tolerate motion.
Kastle and Konecny used an approach referred to as noise-mix-composition. In this approach, 136 different combinations of raw patient-generated signals from the operating room, the intensive care unit, and the PACU were used. The range of oxygen saturation in the signals was 39% to 100% (mean 89.9%; SD 10.7%), and the range of pulse rates was 49/min to 201/min (mean 108.2/min; SD 45.9/min). These signals were then fed digitally into each of the pulse oximeters being studied. The advantage of this approach is that real, not simulated, signals were used. In addition, a wide range of both oxygen saturations and pulse rates were used to test the pulse oximeters. This range of values more closely approximated the types of clinical phenomena encountered in the critical care setting.

In general, the overall results of the 5 laboratory studies were consistent. In studies in which passive motion was used, the Masimo SET device tended to have the best performance, whereas in studies in which active motion was used, the Nellcor and Philips devices tended to have the best performance. For example, in the study by Kastle and Konecny, the Masimo device had the best performance (2.6-fold improvement over conventional pulse oximeters compared with 1.6-fold improvement for both Philips and Nellcor) during the steady-state reference hand, passive-motion part of the study.
testing. In contrast, during the noise-mix-composition, active-motion part of the study, the Philips device had the best performance (1.6 fold improvement compared with 1.5-fold for the Masimo device and 1.3-fold for the Nellcor device). However, none of these differences were clinically significant.

In 4 of the 5 laboratory studies, conventional devices were used as one means of comparison. A consistent and important finding of these 4 studies was that regardless of the differences in measurement criteria, the performance of all the new-generation pulse oximetry devices was better than the performance any of the conventional devices to which they were compared.

**Clinical Studies in Adults**

Real clinical environments and adult patients were used to assess the performance of new-generation pulse oximeters in 6 studies. The new-generation devices included the Masimo SET, Nellcor N-3000, and Philips FAST SpO₂. The clinical areas included the operating room, the PACU, the ICU, and the critical care unit. Because patients’ movements...
should not be a factor in the operating room, we consid-
ered studies done in the operating room separately from
those done in the PACU or critical care unit.

The new-generation devices used in the operating
room included the Nellcor N-3000 and the Philips
FAST SpO₂. In the first study, Rheineck-Leyssius and
Kalkman⁴ found no difference found between the per-
formance of the N-3000 with a 5- to 7-second signal-
averaging time and the performance of a conventional
pulse oximetry device with a 21-second signal-averag-
ing time.

### Table: Findings and Comments

<table>
<thead>
<tr>
<th>Part I</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission rates to a special care nursery or a regular nursery were compared for matched infants who did (experimental, n=25) or did not (control, n=25) have SpO₂ monitoring in the delivery suite</td>
<td>Sample selection was biased because of a lack of randomization of subjects into groups</td>
</tr>
<tr>
<td>The rate of admission to the special care nursery was significantly higher for infants in the control group</td>
<td>The poorly described methods, particularly for dependent variables and matching of the control group, limit evaluation of the study</td>
</tr>
<tr>
<td>The performance of the Masimo SET was better than that of the Oxismart; the percentage of minutes with continuous data output was significantly higher for the Masimo SET</td>
<td>Difference in “continuous data” variable could be due to different manufacturers' approaches to data display during potential artifact conditions</td>
</tr>
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<table>
<thead>
<tr>
<th>Part II</th>
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<tr>
<td>The effects of pulse oximetry monitoring on immature infants were evaluated</td>
<td>The lack of simultaneous Sao₂ data makes interpretation of the study results difficult</td>
</tr>
<tr>
<td>The signal adequacy in the delivery suite of the MT device and the CPO was compared</td>
<td>Part II</td>
</tr>
<tr>
<td>The time from delivery to adequate signal for the MT device was compared</td>
<td>The poorly described methods, particularly for dependent variables, limits the study findings</td>
</tr>
<tr>
<td>Mean time from delivery to adequate signal was 2.3 minutes (range 1-5.3 minutes)</td>
<td>A weakness was that they did not do anything with the experimental and control groups in Part II</td>
</tr>
<tr>
<td>All of the 15 infants had an initial reliable pulse oximetry signal</td>
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<tr>
<td>The N-3000 had the best performance, with fewer false alarms and dropouts than the N-200</td>
<td>No gold standard was used</td>
</tr>
<tr>
<td>The alarm rates for the 3 devices studied in each of the populations of patients were evaluated</td>
<td>The 2 new-generation devices were not compared with each other</td>
</tr>
<tr>
<td>No statistical or clinical differences were detected between any of the devices studied for true-positives, false-positives, and false-negatives for the PACU and ICU parts of the study</td>
<td>No gold standard was used to assess accuracy of SpO₂ readings</td>
</tr>
</tbody>
</table>
| In the PACU and ICU, although some individual differences between devices for types of alarm (true-positive, false-positive, false-negatives, true-negative, inoper-
active) were detected, the overall performance of the devices was comparable | Very limited information was provided on how clinicians determined the true and false alarms |
| During IABP, no devices performed well (although the errors were different); therefore, pulse oximetry is probably not very accurate during IABP | No alarm thresholds were specified |
| The Masimo SET detected 100% of true alarms (27), accounted for 4 of 31 false alarms, and had a positive predictive value of 87% | The software revision for the Philips CMS was not specified, so it is difficult to be sure that it was an MT device |
| The N-200 detected 59% of true alarms, accounted for 10 of 26 false alarms, and had a positive predictive value of 61% | |
| Data dropout was similar for both devices | No gold standard was used |

None of the new-generation oximeters differed from the others in clinical performance.

Signal-averaging time for pulse oximeters repres-
ents the amount of time (in seconds) used by the device
to calculate the displayed SpO₂ value. The shorter the
signal-averaging time, the more sensitive the device will
be to changes in the SpO₂ value. However, the device
will also be more prone to false alarms due to artifact
or error. Conversely, as the signal-averaging time is increased, the number of alarms due to error or artifact is decreased, but the amount of time needed to detect a true hypoxemia is concomitantly increased, because the SpO₂ values are averaged over a longer period.

Hence, the results of the study²³ are not surprising because patients’ movements should not be a factor in the operating room. Furthermore, a 21-second signal-averaging time on the conventional comparison device would obscure most of the signal artifact because the signal is averaged over such a long period. In contrast, in most of the new-generation devices, signal-averaging times are less than 10 seconds. This decrease in time enhances detection of hypoxemia, and, at the same time, the improved algorithms are better able to filter out motion artifacts due to patients’ movements, thus helping to control for the increase in false alarms that accompany decreased signal-averaging times with conventional pulse oximetry.

Factors that influenced oximeters’ degree of error were peripheral temperature, finger thickness, hemoglobin concentration, and skin color.

In the second study done in the operating room, Wouters et al²⁵ used a total of 2694 SpO₂ recordings in 1483 patients and compared the measurement accuracy of the Philips FAST SpO₂ and the Nellcor N-3000. Values obtained via co-oximetry were used as the reference SpO₂ measurements. The overall results indicated

<table>
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<tr>
<th>Study</th>
<th>Devices</th>
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<tr>
<td>Poets et al²²</td>
<td>Nellcor N-100 and N-200 (CPO) Ohmeda 3700 (CPO) Nellcor N-3000 (MT) Philips (CPO) Masimo SET (MT)</td>
<td>A total of 267 patients in an NICU</td>
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<tr>
<td>Rheineck-Leyssius and Kalkman²³</td>
<td>Nellcor Symphony N-3000 with Oxismart (MT) Criticare 504 (CPO) with signal-averaging time at 21 seconds Criticare 504 (CPO) with signal-averaging time at 3 seconds</td>
<td>53 operating room patients</td>
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<td>603 patients in a PACU</td>
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<tr>
<td>Wouters et al²⁵</td>
<td>Philips FAST on CMS Nellcor N-3000 (MT) Arterial blood gas analysis</td>
<td>1483 perioperative patients at 4 sites</td>
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</tbody>
</table>

Abbreviations: CPO, conventional pulse oximeter; IABP, intra-aortic balloon pumping; ICU, intensive care unit; MT, motion tolerant; NICU, neonatal intensive care unit; PACU, postanesthesia care unit; SaO₂, arterial oxygen saturation; SpO₂, oxygen saturation measured by pulse oximetry.
accurate, comparable, and clinically acceptable performance for both devices, with neither device outperforming the other. In addition, this study was the only one in which multivariate analyses were used to determine other patient-related variables that might affect the performance of pulse oximetry devices. Four variables had a significant effect on the degree of error of both pulse oximeters: peripheral temperature, finger thickness, hemoglobin concentration, and skin color.

Although finger thickness was addressed in a few of the studies by rotating the placement of the sensor on the patient’s finger (see Table), none of the other variables was addressed. These variables should be included and analyzed in all future studies on pulse oximeters.

The new-generation Masimo SET, Philips FAST SpO₂, and the Nellcor N-3000 devices were used in the studies done in the PACU and the critical care unit. For these studies as a group, two overall conclusions can be made. First, the performance of the Masimo SET and the Nellcor N-3000 devices was significantly better than that of the comparison conventional devices. Second, when compared with one another, none of the new-generation devices differed significantly in clinical performance.

Lutter et al²⁰ compared the performance of Masimo SET, Nellcor N-3000, and Philips FAST SpO₂ devices during intra-aortic balloon pumping in the intensive care unit. They found that all 3 devices had degradations in clinical performance during pumping, suggesting that SpO₂ measurements in general should be used with caution during pumping. This finding seems reasonable, because intra-aortic balloon pumping creates a rhythmic disturbance in the arterial waveform that is in sync with the cardiac cycle, thereby making it diffi-
cult for pulse oximetry devices to distinguish between a true cardiac signal and the “artifact” signals generated by the intra-aortic balloon pump.

Clinical Studies in Children

The Masimo SET and the N-295 (Nellcor’s earliest motion-tolerant pulse oximetry device) devices were used in 2 clinical studies done in children.11,21 Malviya et al12 studied a group of 75 healthy children in a PACU and compared the Masimo SET device with a conventional Nellcor N-200 pulse oximeter. No gold standard was used and only a single new-generation pulse oximetry device was used. However, the findings from this study were consistent with the results from all other studies; the clinical performance of the motion-tolerant Masimo SET was better with regard to both true and false alarm conditions than was the comparison conventional device. Brouillette et al11 compared the Masimo SET with the Nellcor N-200 and N-395 in children in a sleep laboratory. Unfortunately, this study was so methodologically flawed that no meaningful conclusions can be made. Significant weaknesses included discrepancies in the reported signal-averaging times of the devices and lack of a gold standard reference SpO2 value, making it impossible to assess accuracy for either device.

Clinical Studies in Patients in the Neonatal Intensive Care Unit

A total of 3 studies16,15,14 were done in patients in the neonatal intensive care unit (NICU). The motion-tolerant devices used in these studies included the Philips FAST SpO2, the Masimo SET, and the Nellcor N-3000. One study14 was so poorly designed and had such ambiguous findings that it was excluded from this review. Bohnhorst et al10 compared the Masimo SET and the Nellcor N-3000 motion-tolerant devices with each other and with the Nellcor N-200 conventional device. The performance of both of the motion-tolerant devices was better than that of the comparison conventional devices, again consistent with findings from previous studies. In addition, when the 2 motion-tolerant devices were compared with each other, the performance of the Masimo SET was significantly better than that of the Nellcor N-3000 for correct alarms, detection of hypoxia, and detection of bradycardia. These data indicate that the overall alarm rate for the N-3000 may have been achieved at the expense of some missed alarms for hypoxemia. If true, this possibility is clearly something that would be a point of concern for critical care clinicians. However, because the rate of false alarms was not evaluated in this study, fully evaluating the performance of each of the devices in the study is difficult.

More specifically, in a recent study, Hay et al13 examined the performance of the Philips FAST SpO2, Masimo SET, and the Nellcor N-395 devices and compared them with conventional devices for detection of hyperoxemia. The number of false alarms (specificity) and data dropouts did not differ significantly between the new-generation devices, and the Masimo SET had the best overall clinical performance. However, the software revision of the Philips device was not provided, again making a meaningful comparison difficult.

An important clinical issue specific to patients in the NICU is the performance of new-generation motion-tolerant pulse oximetry devices in detecting hyperoxemia.22 Hyperoxemia in the NICU is generally defined as a PO2 greater than 80 mm Hg, and only a few investigators attempted to determine the appropriate alarm level of pulse oximetry devices needed for detection of hyperoxemia. Hyperoxemia is associated with a number of complications in neonates, including retinopathy of prematurity, a complication that is not a clinical concern in children and adults. Poets et al22 reported that at an upper alarm limit of 95%, new-generation pulse oximeters are much better than the older generation devices in detecting hyperoxemia.

Summary

A consistent finding among the studies reviewed was the superior performance with regard to reduction in frequency of false alarms and overall accuracy of all the new motion-tolerant devices compared with the performance of the various conventional pulse oximeters. However, more clinical evidence on the performance of new-generation pulse oximetry devices is clearly needed, particularly in the setting of critical care. Although some conclusions can be made, a lack of consistency among study variables and techniques and discrepancies between the results of the studies reviewed make it difficult to make any overall recommendations about which of the new-generation motion-tolerant devices are best suited for use in critical care in any of the populations of patients studied. Clearly, more clinical trials are needed before the most accurate and reliable motion-tolerant pulse oximetry device can be determined for use in populations of critically ill patients. These trials should address the performance of the algorithms used for obtaining SpO2 values in critically ill patients of all ages in situations in which patients’ movements are a factor. In addition, each trial should clearly specify which software revisions are being used with each device and should include a comparison with a known gold standard (preferably co-oximetry) for measurement of oxygen saturation. Finally, on the basis of the findings from Wouters et

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al, the variables of peripheral temperature, finger thickness, hemoglobin concentration, and skin color should be part of every future study on measurement of oxygen saturation by pulse oximetry devices to further assess the significance of these variables on clinical measurement of SpO₂.

**New-generation oximeters have fewer false alarms and higher accuracy than do conventional oximeters.**

New technology has, without doubt, advanced the science of pulse oximetry. Evidence supports the contention that the performance of the new-generation devices with incorporated enhanced algorithms for SpO₂ monitoring is superior to the performance of conventional pulse oximeters. However, until more evidence is available from clinical studies in which the new-generation oximeters are compared with one another, no valid judgments or decisions can be made about which new-generation device has the best clinical performance in different populations of critically ill patients.

Commentary by Mary Jo Grap (see shaded boxes).

**REFERENCES**


CE Test Instructions

To receive CE credit for this test (ID# A051401), mark your answers on the form below, complete the enrollment information, and submit it with the $13 processing fee (payable in US funds) to American Association of Critical-Care Nurses (AACN). Answer forms must be postmarked by January 1, 2007. Within 3 to 4 weeks of AACN receiving your test form, you will receive an AACN CE certificate.

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New-Generation Pulse Oximetry in the Care of Critically Ill Patients

Objectives
1. Compare and analyze new-generation pulse oximeters with conventional devices
2. Describe the devices that showed superior clinical performance in the studies involving adults in the postanesthesia care unit, critical care unit, and operating room
3. Describe the devices that showed superior clinical performance in the studies involving children and neonates

Mark your answers clearly in the appropriate box. There is only one correct answer. You may photocopy this form.

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CE Test Questions

New-Generation Pulse Oximetry in the Care of Critically Ill Patients

1. What are the advantages of conducting a clinical study in a laboratory setting rather than in a real clinical setting?
   a. Shorter time, fewer ethical concerns
   b. Lower cost, more control over variables
   c. Ease of replicating clinical area, use of volunteers
   d. Lack of research approval, ease of reproducibility

2. What is a disadvantage of using the steady-state reference hand method?
   a. Excessive patient movement
   b. Cost of robotic arm
   c. Use of passive motion
   d. Positive correlation to clinical setting

3. What was a weakness of the Jopling and Gerhing studies?
   a. Simulated clinical setting
   b. The studies were performed in a critical care area
   c. Small sample size
   d. Low cost

4. What is one of the differences between conventional devices and new-generation devices?
   a. Conventional devices are less prone to false alarms.
   b. New-generation devices are motion tolerant.
   c. New-generation devices are more prone to false alarms.
   d. Conventional devices are motion tolerant.

5. What did the overall findings of the Jopling and Gerhing studies indicate?
   a. When the new-generation devices were compared with one another, differences in the detection of hypoxemia were not significant.
   b. The performance of the conventional devices was better than that of the new-generation devices.
   c. The performance of the new-generation devices was better than that of the conventional devices.
   d. Both A and C are correct

6. What type of study approach did Kastle and Konecny employ?
   a. Steady-state reference hand
   b. Active motion protocols
   c. Noise-mix-composition
   d. Passive motion protocols

7. Why were studies in the operating room considered separately from studies conducted in other areas of the hospital?
   a. Operating room is a more controlled environment
   b. Anesthesia controlled oxygenation
   c. Patients’ movements are not a factor in the operating room
   d. Most surgical patients are stable

8. Which of the following statements regarding pulse oximetry devices is true?
   a. The longer the signal-averaging time, the more sensitive the device will be to changes in the SpO2 value.
   b. The shorter the signal-averaging time, the more sensitive the device will be to changes in the SpO2 value.
   c. The longer the signal-averaging time, the less sensitive the device will be to changes in the SpO2 value.
   d. Both B and C are correct

9. What was one of the weaknesses of the Malviya study?
   a. Use of multiple pulse oximeters
   b. Lack of a gold standard reference SpO2 value
   c. Small study size
   d. No critically ill children were studied

10. Which of the following neonates would be classified as hyperoxemic?
    a. A neonate with PaO2 75 mm Hg
    b. A neonate with PaO2 90 mm Hg
    c. A neonate with PaO2 70 mm Hg
    d. A neonate with PaO2 65 mm Hg

11. Hyperoxemia in neonates is associated with which of the following complications?
    a. Retinopathy of prematurity
    b. Bronchopulmonary fistula
    c. Congenital heart disease
    d. Both B and C are correct

12. According to the authors, which of the following variables should be addressed in future studies on pulse oximeters?
    a. The performance of the algorithms used for obtaining SpO2 values in moving patients
    b. Trials should clearly specify which software revisions are being used with each device
    c. Only pulse oximetry should be used to measure oxygen saturation
    d. Both A and B are correct
New-Generation Pulse Oximetry in the Care of Critically Ill Patients
Karen K. Giuliano and Thomas L. Higgins

Am J Crit Care 2005;14 26-37
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